Human Research Protection Program

Annual Meeting

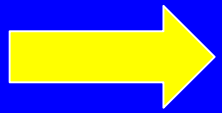
May 2, 2002

Topics

- Investigator Assurances
  -consents
  -FLAGS
- Belmont Report
- Common Rule
- FWA
- Certification
- PI office files

Cultural Change

Oversight & regulatory process are a burden to research, need to be reduced to a minimum



Regulations are for patient safety, bring value to research enterprise

Investigator's Assurances

- Report changes
- Report adverse events
- Original, signed informed consent to Research Service (WITHIN 48 HOURS)
- Comply with periodic review
- Activate FLAG (IMMEDIATELY)
- PI responsible for the ethical conduct of project

Informed Consent Document

Full name and full social security number on each page

Approved Consent Forms

- Approval date now stamped on all consent forms
- Never consent a patient unless the form is stamped with the most recent IRB approval date.
- Use as master set for copying

Changes to Continuing Review

- Updated abstract to be required at the time of IRB continuing review (rather than at time of annual review by R&D Committee)

Clinical Research at PVAMC

- # of investigators = 104
- # of protocols = 367
- # of active FLAGS = 454

Stratification by Risk

- Minimal
- Moderate *
- High *

* Requires FLAG activation

Activating FLAGS

- Activate as soon as the patient is consented
- Currently can only activate a FLAG through VISTA
- Project underway to be able to activate FLAGS directly from CPRS

What does FLAG do for Clinician?

- Immediately apparent at each clinical encounter
- Describes research, gives contacts
- Separate entry for experimental drug forms
- Activation process alerts PCP
- Safety - prevents accrual into more than on moderate or high risk protocol

Research Service Support for Human Studies

IRB Coordinators: Sola Whitehead and Lisa Gunion-Rinker

R&D Committee - IRB Integration: Margaret Doherty

Research Assurance and Compliance Coordinator: Angie Lacey

IRB Chair: Dennis Mazur

Forms Change Frequently

- For each new project, request latest forms (via email) from Research Service office
- Project Revision/Amendment Form and Adverse Event forms are same as those used by OHSU (http://ohsu.edu/ra/forms.shtml#hsf)

Deadline

20th of each month
Complete application (including PPQ and Administrative Review)

Accountability to General Public

- Research funding depends on trust and support

- 60 institutions in the last 3 years have been criticized by OHRP for failing to protect human subjects adequately

- 83% of Americans believe new drugs must be tested in humans*

- 24% of Americans are very confident that patients in clinical trials are not treated as guinea pigs*

*Harris Interactive Poll, February 2002

Accountability

1. Belmont Report
2. Common Rule
3. Federal Wide Assurance (FWA)

Belmont Report

- Respect for Persons
  -individual autonomy
  -protection of individuals with reduced autonomy
- Beneficence: risk/benefit assessment
  - “do no harm”
  - “maximize benefits and minimize risks”
- Justice
  -fairness in selection of subjects

Respect for Persons
The Consent Process

Informed consent is not a single event or just a form to be signed — rather it is an educational process that takes place between the investigator and the prospective subject

- full disclosure of the nature of the research and the subject's participation
- adequate comprehension on the part of the potential subjects
- the subject's voluntary choice to participate

Beneficence

- Risk: the possibility that harm may occur
- Benefit: something of positive value for health or welfare

Personal Risk vs Societal Benefit

Justice

- Selection needs to be scrutinized
- Diverse populations/groups must be included
- Individuals with compromised capacity should be protected

IRB Decision Matrix

Beneficence

Risk/Benefit Analysis

Experimental Design

Qualifications of PI

Justice

Subject Selection
Inclusion/Exclusion
Recruitment

Respect for Persons

Informed Consent
Surrogate Consent
Assent

Protection of Subjects (especially vulnerable populations)

Federal Regulations and Policy

"The Common Rule"

-Review of research by an IRB

-Informed consent of subjects

-Institutional assurances of compliance

Institutional Review Board (IRB)

- Dennis Mazur, Chair
- Wayne Clark
- William Hoffman
- Ronald Brown
- Mark Deffebach
- Susan Hart
- Steven Hefeneider
- John McDermott
- Sue Millar
- William Tuttle
- William Wickham
- Beverly Jefferson
- Richard Jones
- Vickie Vonderohe
- Richard Yeager

FEDERALWIDE ASSURANCE (FWA) OF PROTECTION FOR HUMAN SUBJECTS

- Institution will abide by Belmont Report
- IRB will comply with Common Rule
- Written Informed Consent for all human subject research
- IRB has written operating procedures
- Education of IO, IRB Chair, Human Protections Admin., IRB staff and PIs
- Institution provides IRB with resources, staff and space

Certification to Participate in Research with Human Subjects

- Applies to PIs and all team members involved in research protocols

- Documents a basic fund of knowledge on the Belmont Report, Common Rule, Financial Conflict of Interest and VA-specific regulations

Options for Certification

1. U. of Miami on-line course and post test

2. Training provided by the Portland VA Research Service (with a post test) plus

-University of Rochester course & test

or

-NIH web-based course and test

VA Initiatives to Demonstrate Accountability

ORCA

NCQA

Guidance to PIs

Study Documentation & Organization

Current Active Research Projects

Maintain a list containing the following information:

1. Title
2. Funding Source
3. VA and/or OHSU assigned protocol numbers
4. All individuals staffing each project

Research Project Binder

1. Original protocol and all amendments
2. Approval Correspondence - IRB and R&D Committee
3. Consent Form (most recent and every version)
4. Study related correspondence - sponsor, FDA, data monitoring board, etc.
5. Adverse events - all forms
6. Training records
7. Misc. - audits, lab accreditation,

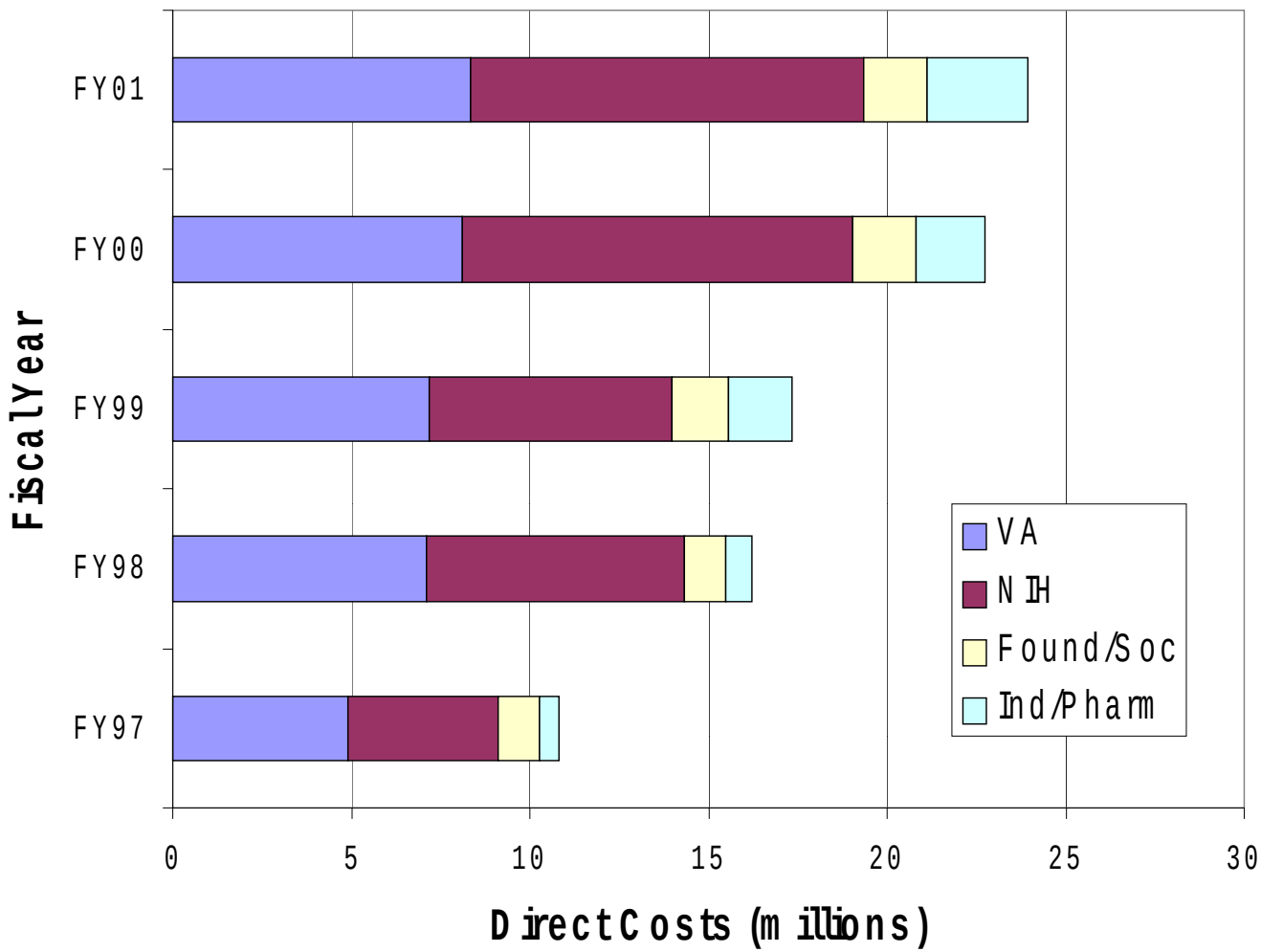
Patient Study Files

Maintain a file for each study patient that includes:

1. screening information
2. copy of signed consent form
3. randomization data
4. study visits
5. correspondence with patient
6. statement of why a patient may have withdrawn

Device or Drug Studies

- see Angie Lacey for advice on how to set up special files in your office related to devices and drugs


Research Support
FY01
FY00
FY99
FY98
FY97
Fiscal Year
0
5
10
15
20
25
30
Direct Costs (millions)
VA
NIH
Found/Soc
Ind/Pharm

Summary: PVAMC Commitments

- Foster a culture of "ethical principles"
  -PIs must focus on ethics as much as methods
  -Placebo, populations at risk, subtle coercion, $
- Support the IRB and its mission
- Promote education
  -PIs must understand and follow federal regulations
- Zero tolerance for non-compliance